



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-1557, CMS-10531 and CMS-10535]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A))

requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations; Use: The form is used to report surveyor findings during a CLIA survey. For each type of survey conducted (i.e., initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. Form Number: CMS-1557 (OMB control number: 0938-0544); Frequency: Biennially; Affected Public: Private sector (Business or other for-profit and Not-for-profit institutions, State, Local or Tribal Governments and Federal Government); Number of Respondents: 19,051; Total Annual Responses: 9,526; Total Annual Hours: 4,763. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385).

2. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, “Transcatheter Mitral Valve Repair (TMVR)”. The TMVR device is only covered when specific

conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all-cause mortality and quality of life.

We find that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TMVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TMVR technologies for the treatment of mitral regurgitation (MR). The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ-10) to assess health status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ-10 is pursuant to section 1142 of the Social Security Act (the ACT) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional

data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used to determine if TMVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under section 1862(a)(1)(A) of the ACT. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat mitral regurgitation. For purposes of the TMVR NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. Form Number: CMS-10531(OMB control number: 0938-NEW); Frequency: Annually; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 4,000; Total Annual Responses: 16,000; Total Annual Hours: 5,600. (For policy questions regarding this collection contact Roya Lotfi at 410-786-4072.)

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Employer Notification to HHS of its Objection to Providing Coverage for Contraceptive Services; Use: The proposed rules titled “Coverage of Certain Preventive Services Under the Affordable Care Act” (79 FR 51118), if finalized as proposed, would require each qualifying closely-held, for-profit entity seeking to be treated as an eligible organization to provide notification of its religious objection to coverage of all or a subset of contraceptive services. Issuers and third party administrators providing or arranging payments for contraceptive services for participants and beneficiaries in plans of eligible organizations

would be required to meet the notice requirements as set forth in the 2013 final regulations, requiring them to provide notice of the availability of separate payments for contraceptive services to participants and beneficiaries in the eligible organizations' plans (78 FR 39870, 39880 (July 2, 2013)).

The interim final regulations titled "Coverage of Certain Preventive Services Under the Affordable Care Act" (79 FR 51092) continue to allow eligible organizations that have religious objections to providing contraceptive coverage to notify an issuer or third party administrator using EBSA Form 700, as set forth in the 2013 final regulations. In addition, these interim final regulations permit an alternative process under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services.

Form Number: CMS-10535 (OMB control number: 0938-1248); Frequency: Once; Affected Public: Private sector (Business or other for-profits and not-for-profit institutions); Number of Respondents: 61; Number of Responses: 61; Total Annual Hours: 51. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650.)

Dated: March 2, 2015.

William N. Parham, III,
Director,
Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

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